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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO.                                 | CONFIRMATION NO.                          |
|---|-------------|------------------------|---|---|
| 10/733,064  | 12/11/2003  | Alexander Sulakvelidze | 62610.000044  | 7824                                      |
| <div>21967      7590      11/13/2007</div> <div>HUNTON &amp; WILLIAMS LLP<br/>INTELLECTUAL PROPERTY DEPARTMENT<br/>1900 K STREET, N.W.<br/>SUITE 1200<br/>WASHINGTON, DC 20006-1109</div> |             |                        |   |   |
|   |             |                        | <div>EXAMINER</div> <div>KINSEY WHITE, NICOLE</div> |   |
|   |             |                        | <div>ART UNIT</div> <div>1648</div>                 | <div>PAPER NUMBER</div>                   |
|   |             |                        | <div>MAIL DATE</div> <div>11/13/2007</div>          | <div>DELIVERY MODE</div> <div>PAPER</div> |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |   |  |  |
|------------------------------|---|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/733,064          | <b>Applicant(s)</b><br>SULAKVELIDZE ET AL. |  |
|                              | <b>Examiner</b><br>Nicole Kinsey White, Ph.D. | <b>Art Unit</b><br>1648                    |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 43-48 and 88-97 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-48 and 88-97 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on September 4, 2007 has been entered.

### ***Withdrawn Rejections***

The rejection of claims 40-42 and 90-93 under 35 U.S.C. 102(b) as being anticipated by Taylor et al. (U.S. Patent No. 2,851,006) has been withdrawn in view of applicants' cancellation of claims 40-42 and applicants' amendments to claims 90-93.

The rejection of claims 46-48 under 35 U.S.C. 102(b) as being anticipated by Day et al. (U.S. Patent No. 4,851,240) has been withdrawn in view of applicants' arguments and in view of applicants amendments to the claims. Day et al., which discloses treating ruminant livestock with bacteriophage, does not teach treating poultry livestock with bacteriophage.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 43-45 and 88-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merrill et al. (U.S. Patent No. 5,811,093) in view of Byrd et al. (Applied Poultry Science, 1998, 7:75-80), Taylor et al. (U.S. Patent No. 2,851,006) and Berchieri et al. (Res. Microbiol., 1991, 142:541-549) and as evidenced by Holzman (Genetic Engineering News, 1998, 18(18)).

The claims are drawn to a method for poultry processing sanitation with at least one bacteriophage, comprising: applying the at least one bacteriophage to at least one

freshly-hatched bird before transferring said at least one freshly-hatched bird to a chicken house.

Merril et al. discloses topically treating animals (e.g., man, domestic pets, livestock, pisciculture, and animals in zoos and aquatic parks) with a composition comprising bacteriophage to kill bacteria (see col. 9, line 42 to col. 11, line 3). It is common knowledge that chickens, including newly hatched chicks, are livestock (The Cambridge Dictionary of American English defines livestock as "animals kept on a farm, such as cows, sheep, chickens, and pigs." Further, Holzman, quoting Dr. Alexander Sulakvelidze, a current inventor, states that "Intralix plans to target pathogens that plague livestock, such as *Salmonella* in meat, poultry and eggs.") The phage formulations are for the prevention and treatment of bacterial infection in humans and animals, and the routes of administration include, oral, aerosol or other device for delivery to the lungs, nasal spray, intravenous, intramuscular, intraperitoneal, intrathecal, vaginal, rectal, and topical (see col. 10, lines 58-62).

Merril et al. does not disclose the use of a cocktail of bacteriophage or applying the bacteriophage specifically to a freshly-hatched bird.

Byrd et al. teaches that boiler breeder flocks and hatcheries are reservoirs of salmonellae and potential sources of *Salmonella* infection for day-old chicks. Byrd et al. further teaches that *Salmonella* is shed into the environment to contaminate it and to colonize other chicks and that *Salmonella* contamination occurs in essentially all phases of broiler production (see Abstract and Introduction).

Berchieri et al. teaches that chicks are infected with a variety of serotypes of *Salmonella* within a few hours of hatching (see page 142, Introduction).

Taylor et al. discloses using cocktails of bacteriophage to assure the destruction of all possible species of bacteria, namely *Salmonella* (col. 2, lines 25-44).

Holzman discloses using bacteriophage to target pathogens that plague livestock, such as *Salmonella* in meat, poultry and eggs as a way of potentially clearing the poultry yards of *S. enteritidis*. Holzman states that "[u]p to 75% of human cases are acquired from meat, poultry or eggs, and up to 25% of broiler chickens and 18% of turkey carry that organism." (see page 48 of Holzman).

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Merrill et al. and use a cocktail of bacteriophage. One would have been motivated to do so given the suggestion by Taylor et al. that cocktails of phages should be used to assure the destruction of all possible species of bacteria. There would have been a reasonable expectation of success given the knowledge that phages kill bacteria and also given the knowledge that more than one strain, serotype or species of bacteria can contaminate/infect an animal as evidenced by Berchieri et al.

It would have also been obvious to one of ordinary skill in the art to use the method taught by Merrill et al. to topically apply the bacteriophage composition to chickens, including freshly-hatched chicks, and eggs. One would have been motivated to do so, given the suggestion by Holzman to use phages to target pathogens that plague livestock, such as *Salmonella* in meat, poultry and eggs, and *E. coli* 0157, and given the teachings of Berchieri et al. (chicks are infected within a few hours of

hatching) and Byrd et al. (*Salmonella* is shed by contaminated chicks into the environment to contaminate it and to colonize other chicks and that *Salmonella* contamination occurs in essentially all phases of broiler production). There would have been a reasonable expectation of successfully disinfecting a freshly-hatched chick because i) chicks are contaminated with bacteria soon after hatching and ii) bacteriophage are known to kill bacteria.

The recitation "a method for poultry processing sanitation" is an intended use of the process. A recitation of intended use of the claimed invention must result in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim limitations. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458,459 (CCPA 1963). Here, the combined teachings of Merrill et al., Berchieri et al., Byrd et al., Holzman and Taylor et al. (administering a phage cocktail topically to livestock including chickens) is capable of performing the intended use of the instant claims (sanitizing poultry).

Thus, the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 46-48 and 94-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merrill et al. (U.S. Patent No. 5,811,093) as applied to claims 43-45 and 88-89 above, and further in view of Day et al. (U.S. Patent No. 4,851,240), Taylor et

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al. (U.S. Patent No. 2,851,006), Byrd et al. (Applied Poultry Science, 1998, 7:75-80) and Berchieri et al. (Res. Microbiol., 1991, 142:541-549).

The claims are drawn to a method for poultry processing sanitation with at least one bacteriophage, comprising: applying the at least one bacteriophage to at least one freshly-hatched bird before transferring said at least one freshly-hatched bird to a chicken house, wherein drinking water and food comprising at least one bacteriophage is provided to the bird.

The teachings of Merrill et al., Byrd et al. and Berchieri et al. are outlined above.

Merrill et al. further teaches that the phage formulations can be administered orally to humans and livestock for the prevention and treatment of bacterial infections (see col. 10, lines 58-62). Merrill et al. does not disclose orally administering the phage composition via food or drinking water.

Berchieri et al. further teaches that chicks are infected with a variety of serotypes of *Salmonella* within a few hours of hatching (see page 142, Introduction). Berchieri et al. further suggests that reducing the numbers of *Salmonella* in the gut might reduce not only the associated risk of food-poisoning, but also mortality in the chickens.

Furthermore, Berchieri et al. demonstrated that chickens orally inoculated with *S. typhimurium* and then inoculated with a phage composition showed reduced mortality (see Experimental Plan, p. 543 and p. 545).

Byrd et al. further teaches that day-of-hatch chicks can become colonized by exposure to 100 times fewer *Salmonella* organisms than chicks challenged at Day 3



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resulting in chicks that excrete large numbers of salmonellae into the environment, so that uncolonized chicks become infected during the first week of growout (see page 76).

Day et al. discloses liquid preparation of at least two varieties of bacteriophage, which may be a formulation of phage in food or drinking water, for administering to livestock (see col. 5, line 41 to col. 6, line 5). The phage formulations are for the prevention and treatment of microbial infestations.

Taylor et al. teaches using a cocktail of different phages (col. 2, lines 25-44) to treat fertilized eggs contaminated with *Salmonella* (cocktails of phages should be used to assure the destruction of all possible species of bacteria, namely *Salmonella*).

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Merrill et al. to orally administer a cocktail of bacteriophage as taught by Day et al. and Taylor et al. to livestock (e.g., chickens and freshly-hatched chicks) via drinking water and/or feed. One would have been motivated to do so, given the suggestion by Berchieri et al. that reducing the numbers of *Salmonella* in the gut might reduce not only the associated risk of food-poisoning, but also mortality in the chickens and given the teachings of Berchieri et al. (chicks are infected with a variety of serotypes of *Salmonella* within a few hours of hatching) and Byrd et al. (chicks can become colonized with 100 times fewer *Salmonella* organisms and excrete large numbers of salmonellae that can infect uncolonized chicks). There would have been a reasonable expectation of success given the fact that Berchieri et al. successfully inoculated *Salmonella* infected chicks via the oral route and observed a decrease in

mortality and given the fact that Day et al. used phage-treated feed and drinking water to treat other livestock.

The recitation "a method of poultry processing sanitation" is an intended use of the process. A recitation of intended use of the claimed invention must result in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim limitations. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458,459 (CCPA 1963). Here, the combined teachings of Merrill et al., Berchieri et al., Byrd et al., and Day et al. (administering drinking water or food containing a mixture of phage to livestock (e.g., chickens) is capable of performing the intended use of the instant claims (sanitizing poultry).

Thus, the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 90-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (U.S. Patent No. 2,851,006) in view of Cox et al. (Journal of Applied Poultry Research, 1994, 3:234-237) and Holzman (Genetic Engineering News, 1998, 18(18)).

Taylor et al. discloses submerging fertilized eggs infected with *Salmonella* into fluid containing bacteriophages to disinfect the eggs (see entire document). Example I demonstrates the infection of eggs by submerging the eggs in a chilled culture of *Salmonella chittagong* for 10 minutes and then submerging the infected eggs in a

polyvalent *Salmonella* phage containing liquid for 10 minutes. Clearly, bacteria on the egg will be killed by the phage. Taylor et al. also discloses using a cocktail of different phages (col. 2, lines 25-44).

Taylor et al. does not teach spraying the phage onto the surface of the egg.

Cox et al. teaches that hatching eggs leaving the breeder house usually carry many bacteria: on the shell surface as well as beneath the shell and/or shell membranes. Cox et al. further discloses a spray-sanitizing machine to clean and disinfect eggs using chemical disinfectants.

Holzman teaches using phages to target pathogens that plague livestock, such as *Salmonella* in meat, poultry and eggs, and *E. coli* 0157, as a way of potentially clearing the poultry yards of *S. enteritidis* (see page 48 of Holzman).

It would have been obvious to one of ordinary skill in the art to modify the method taught by Taylor et al. to disinfect contaminated/infected eggs by spraying bacteriophage instead of dipping the eggs into a bacteriophage bath. One would have been motivated to do so given the suggestion by Holzman to use phages to target pathogens that plague livestock, such as *Salmonella* in meat, poultry and eggs, and *E. coli* 0157 and given the teachings of Cox et al. (spraying eggs with a disinfectant reduces the number of bacteria on eggs). One of ordinary skill in the art would reasonably expect that spraying bacteriophage on eggs would successfully disinfect the eggs given the fact that spraying is an efficient method of applying a disinfectant to eggs as taught by Cox et al. and given the fact that Taylor et al. successfully used a phage composition to disinfect contaminated/infected eggs.

The recitation "a method of poultry processing sanitation" is an intended use of the process. A recitation of intended use of the claimed invention must result in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim limitations. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458,459 (CCPA 1963). Here, the combined teachings of Merrill et al., Berchieri et al., Byrd et al., and Day et al. (administering drinking water or food containing a mixture of phage to livestock (e.g., chickens) is capable of performing the intended use of the instant claims (sanitizing poultry).

Therefore, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole Kinsey White, Ph.D. whose telephone number is (571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nicole Kinsey White, Ph.D.  
Examiner  
Art Unit 1648

/nk/

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Art Units 1645 (acting) and 1648